

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: )  
David A. WILLIAMS, et al. )  
Serial No. 09/394,867 )  
Filed: September 13, 1999 )  
METHODS FOR ENHANCED ) Via Hand Delivery  
RETROVIRAL-MEDIATED GENE ) Examiner: Maria Marvich  
TRANSFER ) Group Art Unit 1632

**INFORMATION DISCLOSURE STATEMENT**

**SUBMITTED TO OFFICE AFTER MAILING OF A FINAL OFFICE ACTION  
BEFORE RECEIVING WRITTEN NOTIFICATION OF NEW ISSUES OF  
PATENTABILITY RAISED BY OFFICE AFTER RESPONDING TO SAID FINAL  
OFFICE ACTION**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Please find enclosed an Information Disclosure Statement filed after receiving a Final Office Action on the merits but before the Applicant had an opportunity to respond to a new set of objections raised after Final.

This Information Disclosure Statement is being submitted after the mailing date of a final Office Action and prior to payment of the issue fee, and thus a fee of \$180.00 is enclosed. Should any additional other fee be required, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees. This Information Disclosure Statement is not accompanied by a statement under 37 CFR § 1.98(d) 1. Accordingly the Applicants respectfully

requests pursuant to the provisions of 37 CFR 1.56, 1.97, and 1.98, consideration of the references listed on the attached PTO/SB/08 forms and/or the additional information identified below.

A legible copy of each foreign patent document and publication listed on the PTO/SB/08 form is enclosed.

For each non-English language reference listed on the attached SB/08 form(s), reference is made to:

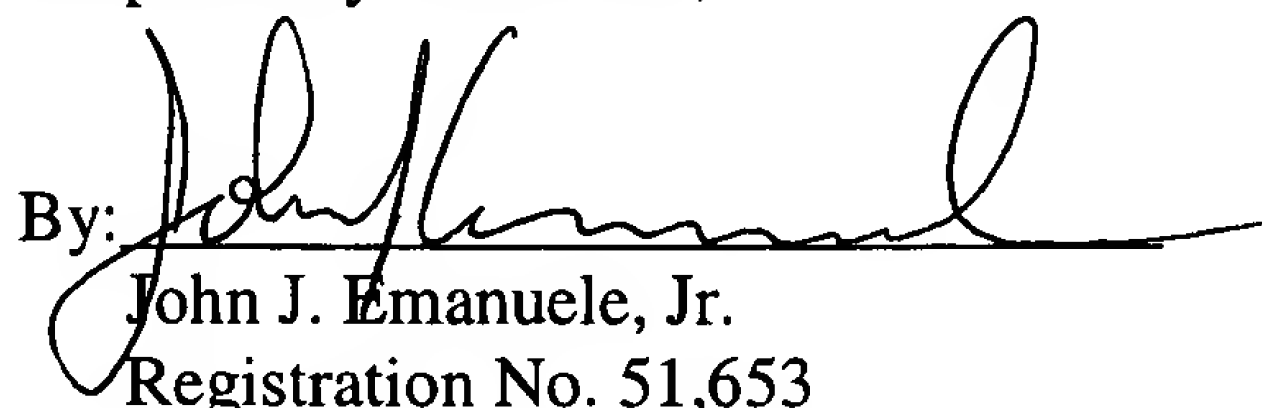
Japanese Patent No. 2-97397 correspondence to European Patent Application Publication No. 0 349 342 A2, a copy of which is also enclosed.

Japanese Publication No. 2-311498 corresponding to Kimizuka et al. U.S. Patent No. 5,102,988, and European Patent Application Publication No. 0 399, 806 A2. A copy of the European publication is enclosed.

The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in §1.56(b).

Respectfully Submitted,

By:



John J. Emanuele, Jr.

Registration No. 51,653

Woodard, Emhardt, Moriarty,

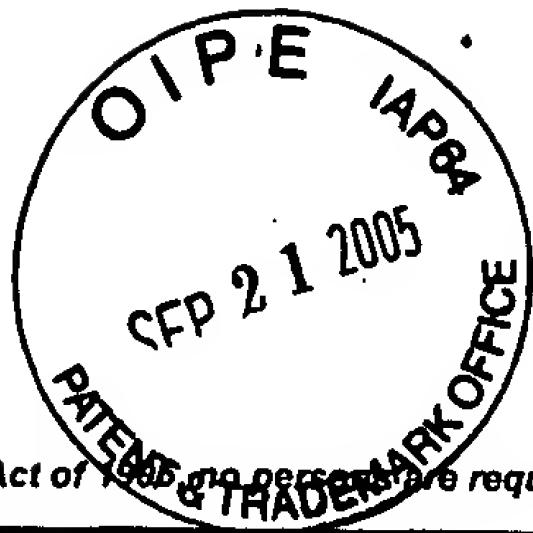
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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/394,867
				Filing Date	9/13/1999
				First Named Inventor	WILLIAMS
				Group Art Unit	1632
				Examiner Name	Maria Marvich
				Attorney Docket Number	7037-377
Sheet	1	of	9		
<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		4,727,059	02-01-1988	Binder	
		4,839,464	06-01-1989	McCarthy	
		4,980,279	12-01-1990	Peters	
		5,004,681	04-02-1991	Boyse	
		5,019,646	05-28-1991	Furcht	
		5,102,988	04-07-1992	Kimizuka	
		5,116,368	05-26-1992	McCarthy	
		5,124,155	06-23-1992	Reich	
		5,175,096	12-29-1992	Hook	
		5,188,959	02-23-1993	Haberman	
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		5,299,172	03-29-1994	Badger	
		5,409,825	04-25-1995	Hoffman	

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		Country Code <sup>2</sup>	Number <sup>3</sup> -Kind Code <sup>5</sup> (if known)				
		EP 0 349 342	A2	01-03-1990	Takara Shuzo Co. Lt		<input type="checkbox"/>
		EP 0 399 806	A1	11-28-1990	Taguchi		<input type="checkbox"/>
		JP 2 311498		12-01-1989	Takara Shuzo Co. Lt		<input type="checkbox"/>
		JP 2 97397		09-04-1990	Takara Shuzo Co. Lt		<input type="checkbox"/>
		WO 90/13641		11-15-1990	Gilboa		<input type="checkbox"/>
		WO 93/18137	A1	09-16-1993	Shih		<input type="checkbox"/>
		WO 94/02610		02-03-1994	Marasco		<input type="checkbox"/>
		WO 95/26200		10-05-1995	Williams		<input type="checkbox"/>

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		T <sup>2</sup>			
		"Bubble Boy saved by gene therapy", BBC News, April 3, 2000			
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		BODINE, D.M. ET AL., "Long-term in vivo expression of a Murine Adenosine Deaminase Gene in Rhesus Monkey Hematopoietic Cells of Multiple Lineages After Retroviral-mediated Gene Transfer into CD34+ Bone Marrow Cells" Blood, 1993, Vol./Issue No. 82:7, pp. 1975-1980			
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		BRADLEY, T.R. ET AL., "The Growth of Mouse Bone Marrow Cells in Vitro", Aust. J. Exp. Biol. Med. Sci., 1966, Vol./Issue No. 44, pp. 287-300			
		BROXMEYER, H.E. ET AL., "Umbilical Cord Blood Hematopoietic Stem and Repopulating Cells in Human Clinical Transplantation", Blood Cells, 1991, Vol./Issue No. 17, pp. 313-329			
		BROXMEYER, H.E. ET AL., "The future of Umbilical Cord Transportation", Umbilical Cord Blood Transportation, , pp. 321-329			
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				Examiner Name	Maria Marvich
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<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published			
		CARTER, ET AL., "Autologous Transplantation of Canine Long-Term Marrow Culture Cells Genetically Marked by Retroviral Vectors", Blood, 1992, Vol./Issue No. 79:2, pp. 356-364			
		CORNETTA, ET AL., "Protamine sulfate as an effective alternative to polybrene in retroviral-mediated gene-transfer: implications for human gene therapy", Journal of Virological Methods, 1989, Vol./Issue No. 23, pp. 187-194			
		CRISTIANO, R.J., ET AL., "Hepatic Gene Therapy: Adenovirus Enhancement of Receptor-Mediated Gene Delivery and Expression in Primary Hepatocytes", Proc. Natl. Acad. Sci. USA, 1993, Vol./Issue No. 90, pp. 2122-2126			
		DILBER, MS. ET AL., "Basic fibroblast growth factor increases retroviral-mediated gene transfer into human hematopoietic peripheral blood progenitor cells", Exp. Hematol, 1994, Vol./Issue No. 22:12, pp. 1129-1133			
		EMONS, G. ET AL., "The Use of Luteinizing Hormone Releasing Hormone Agonists and Antagonists in Gynecological Cancers", Hum. Reprod., 1994, Vol./Issue No. 9:7, pp. 1364-1379			
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		FRIEDMANN, THEODORE, "Progress Toward Human Gene Therapy", SCIENCE, June 1989, pp. 1276-1281			
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		GLUCKMAN, E. ET AL., "Bone Marrow Transplantation in Fanconi Anaemia", British J. of Haem., 1980, Vol./Issue No. 45, pp. 557-564			
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Examiner Initials*	Cite No. 1	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published			T <sup>2</sup>
		HODGSON, CLAGUE P. ET AL., "Virosomes: Cationic Liposomes Enhance Retroviral Transduction", Nature Biotechnology, 1996, Vol./Issue No. 14, pp. 339-342			<input type="checkbox"/>
		HOGGE, DONNA E. ET AL., "The Elusive Peripheral Blood Hemotopoietic Stem Cell", Seminars in Hematology, 1993, Vol./Issue No. 30:4 Supp. 4, pp. 82-89			<input type="checkbox"/>
		HOSHINO, K, "Effects of polycations on infection of human retroviruses", Working Group on Structure and function of HIV, "Working Report of 1993", 1994, Vol./Issue No. Partial Translation, pp. 24-27			<input type="checkbox"/>
		HOWELL, A. ET AL., "Response to a Specific Antioestrogen (ICI 182780) in Tamoxifen—Resistant Breast Cancer", The Lancet, 1995, Vol./Issue No. 345, pp. 29-30			<input type="checkbox"/>
		HOWS, J.M. ET AL, "Growth of human umbilical cord blood in longterm haemopoietic cultures", Lancet, July 11, 1992, Vol./Issue No. 340, pp. 73-76			<input type="checkbox"/>
		KARLSSON, STEFAN, "Treatment of Genetic Defects in Hematopoietic Cell Function by Gene Transfer", Blood, 1991, Vol./Issue No. 78:10, pp. 2481-2492			<input type="checkbox"/>
		KASAHARA, N. ET AL., "Tissue-Specific Targeting of Retroviral Vectors Through Ligand-Receptor Interactions", Science, 1994, Vol./Issue No. 266, pp. 1373-1376			<input type="checkbox"/>
		KIMIZUKA ET AL., "Production and Characterization of Functional Domains of Human Fibronectin Expressed in Escherichia coli", J. Biochem., 1991, Vol./Issue No. 110:2, pp. 284-291			<input type="checkbox"/>
		KLIJN, J.G.M. ET AL., "Pre-Clinical and Clinical Treatment of Breast Cancer With Antiprogestins", Hum. Reprod., 1994, Vol./Issue No. 9 Supp. 1, pp. 181-189			<input type="checkbox"/>
		KOHLI-KUMAR, M. ET AL., "Haematopoietic Stem/Progenitor Cell Transplant in Fanconi Anaemia Using HLA-Matched Sibling Umbilical Cord Blood Cells", British J. Haem., 1993, Vol./Issue No. 85, pp. 419-422			<input type="checkbox"/>
		KORNBLIHTT, A.R., ET AL, "Isolation and characterization of cDNA clones for humans and bovine fibronectin", Proc. Natl. Acad. Sci. USA, 1983, Vol./Issue No. 80:11, pp. 3218-3222			<input type="checkbox"/>
		KORNBLIHTT, A.R., ET AL, "Human fibronectin: cell specific alternative mRNA splicing generates polypeptide chains differing in the number of internal repeats", Nucleic Acids Res., 1984, Vol./Issue No. Abstract 12/14, pp. 5853-5868			<input type="checkbox"/>
		KORNBLIHTT, A.R., ET AL, "Human fibronectin: molecular cloning evidence for two mRNA species differing by an internal segment coding for a structural domain", EMBO J., 1984, Vol./Issue No. Abstract 3/1, pp. 221-226			<input type="checkbox"/>
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		KORNBLIHTT, A.R., ET AL, "Primary structure of human fibronectin: differential splicing may generate at least 10 polypeptides from a single gene", EMBO J., 1985, Vol./Issue No. 4:7, pp. 1755-1759			<input type="checkbox"/>
		LIM, B., ET AL., "Retrovirus-Mediated Gene Transfer of Human Adenosine Deaminase: Expression of Functional Enzyme in Murine Hematopoietic Stem Cells in Vivo", Mol. Cell. Biol., 1987, Vol./Issue No. 7:10, pp. 3459-3465			<input type="checkbox"/>
		LIM, ET AL., "Long-Term Expression Of Human Adenosine Deaminase In Mice Transplanted With Retrovirus-Infected Hematopoietic Stem Cells", Proc. Natl. Acad. Sci. U.S.A., 1989, Vol./Issue No. 86, pp. 8892-8896			<input type="checkbox"/>
		LONG, MICHAEL W., "Blood Cell Cytoadhesion Molecules", Exp. Hematol, 1992, Vol./Issue No. 20, pp. 288-301			<input type="checkbox"/>
		LU, L. ET AL., "CD34 stem/progenitor cells purified from cryopreserved cord blood can be transduced with high efficiency by a retroviral vector and expanded ex vivo with stable integration and expression of fanconi anemia complement c gene" Blood, 1994, Vol./Issue No. Abstract 84/10 Supp. 1, pp. 355a			<input type="checkbox"/>
		LUSKEY, B.D., ET AL., "Stem Cell Factor, Interleukin-3, and Interleukin-6 Promote Retroviral-Mediated Gene Transfer Into Murine Hematopoietic Stem Cells", Blood, 1992, Vol./Issue No. 80:2, pp. 396-402			<input type="checkbox"/>
		MARKOWITZ, D. ET AL., "A Safe Packaging Line for Gene Transfer: Separating Viral Genes on Two Different Plasmids", J. Virol., 1988, Vol./Issue No. 62:4, pp. 1120-1124			<input type="checkbox"/>
		MARKOWITZ, D. ET AL., "Construction and Use of a Safe and Efficient Amphotropic Packaging Cell Line", Virology, 1988, Vol./Issue No. 167, pp. 400-406			<input type="checkbox"/>
		MCGLAVE P. ET AL., "Interaction of primitive human myeloid and lymphoid progenitors with the marrow microenvironment", Blood Cells, 1994, Vol./Issue No. 20:1, pp. 121-128			<input type="checkbox"/>
		MERWIN, JUNE R. ET AL., "Targeted Delivery of DNA Using YEE(GalNAcAH)3, a Synthetic Glycopeptide Ligand for the Asialoglycoprotein Receptor", Bioconjugate Chem., 1994, Vol./Issue No. 5:6, pp. 612-620			<input type="checkbox"/>
		MILLER, A. DUSTY, "Human Gene Therapy Comes of Age", Nature, June 11, 1992, Vol./Issue No. 357, pp. 455-460			<input type="checkbox"/>
		MOORE, KATERI A. ET AL., "Stromal Support Enhances Cell-Free Retroviral Vector Transduction of Human Bone Marrow Long-Term Culture-Initiating Cells", Blood, 1992, Vol./Issue No. 79:6, pp. 1393-1399			<input type="checkbox"/>
		MOORE, M.A., ET AL., "Gene Therapy: New Frontiers, an International Symposium", Meeting Abstract: Dublin, Ireland, Sept. 18-21, 1994, pp. 1-2			<input type="checkbox"/>
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				Filing Date	9/13/1999
				First Named Inventor	WILLIAMS
				Group Art Unit	1632
				Examiner Name	Maria Marvich
				Attorney Docket Number	7037-377
Sheet	7	of	9		
<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>					
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		MOORE, MALCOLM A.S., "Ex vivo expansion of cord blood-derived stem cells and progenitors", Blood Cells, 1994, Vol./Issue No. 20, pp. 468-481			<input type="checkbox"/>
		NGO, ET AL., "The Protein Folding Problem and Tertiary Structure Prediction", 1994, pp. 492-495, Birkhäuser, Boston, US			<input type="checkbox"/>
		NOJIMA, YOSHIHISA ET AL., "Ligation of VLA-4 on T Cells Stimulates Tyrosine Phosphorylation of a 105-kD Protein", J. Exp. Med., 1992, Vol./Issue No. 175, pp. 1045-1053			<input type="checkbox"/>
		OHASHI, T., ET AL., "Efficient Transfer and Sustained High Expression of the Human Glucocerebrosidase Gene in Mice and Their Functional Macrophages Following Transplantation of Bone Marrow Transduced by a Retroviral Vector" Proc. Natl. Acad. Sci. Usa 1992 Vol./Issue No. 89			<input type="checkbox"/>
		PATEL ET AL., "Generation of interleukin-2 Secreting melanoma Cell Populations from Resected Metastatic Tumor", Human Gene Therapy, 1994, Vol./Issue No. 5, pp. 577-584			<input type="checkbox"/>
		PATEL, ET AL., "Loss of Adhesion of Murine Erythroleukemia Cells to Fibronectin During Erythroid Differentiation", Science, 1984, Vol./Issue No. 224, pp. 996-998			<input type="checkbox"/>
		REISBACH, G. ET AL., "Characterization of hemopoietic cell populations from human cord blood expressing c-kit", Exp. Hematol., 1993, Vol./Issue No. 21, pp. 74-79			<input type="checkbox"/>
		RUOSLAHTI, E., "Fibro-nectin: Purification, Immunochemical Properties, and Biological Activities", Methods in Enzymology, 1982, Vol./Issue No. 82, pp. 803-831			<input type="checkbox"/>
		RUOSLAHTI, E., "Fibronectin and Its Receptors", Ann. Rev. Biochem., 1988, Vol./Issue No. 57, pp. 375-413			<input type="checkbox"/>
		RUOSLAHTI, E. ET AL., "Alignment Of Biologically Active Domains in The Fibronectin Molecule", J. Bio. Chem., 1981, Vol./Issue No. 256, pp. 7277-7281			<input type="checkbox"/>
		SAIKI, IKUO ET AL., "Inhibitory effect of fibronectin and its recombinant polypeptides on the adhesion of metastatic melanoma cells to Laminin", Jpn. J. Cancer Res., 1991, Vol./Issue No. 82, pp. 1112-1119			<input type="checkbox"/>
		SEKIGUCHI, K. ET AL., "Human Liver Fibronectin Complementary DNAs: Identification of Two Different Messenger RNAs Possibly Encoding the $\alpha$ and $\beta$ Subunits of Plasma Fibronectin", Biochemistry, 1986 Vol./Issue No. 25 pp. 4936-4941			<input type="checkbox"/>
		SHIH, C-C., ET AL., "Highly Preferred Targets for Retrovirus Integration", Cell, 1988, Vol./Issue No. 53, pp. 531-537			<input type="checkbox"/>
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		SINGH, VINOD ET AL., "Hormonotoxins: Preparation and Characterization of Ovine Luteinizing Hormone-Gelonin Conjugate", Journal of Biological Chemistry, 1989, Vol./Issue No. 264:6, pp. 3089-3095	<input type="checkbox"/>		
		SORRENTINO, BRIAN P. ET AL., "Selection of Drug Resistant Bone Marrow Cells in Vivo After Retroviral Transfer of Human MDR1", SCIENCE, July 3, 1992, Vol./Issue No. 257, pp. 99-100	<input type="checkbox"/>		
		SUTHERLAND ET AL., "Characterization and Partial Purification of Human Marrow Cells Capable of Initiating Long-Term Hematopoiesis In Vitro", Blood, 1989, Vol./Issue No. 74-5, pp. 1563-1570	<input type="checkbox"/>		
		TOKSOZ ET AL., "Support of Human Hematopoiesis in Long-Term Bone Marrow Cultures by Muring Stromal Cells Selectively Expressing the Membrane-Bound and Secreted Forms of the Human Homolog of the Steel Gene Product, Stem Cell Factor" Proc. Natl. Acad. Sci. USA 1992 Vol./Issue	<input type="checkbox"/>		
		TOLCHER, A.W., "Current Status of Post-chemotherapy Tamoxifen in Early Breast Cancer", Oncology, November 1994, Vol./Issue No. 8/11, pp. 39-43	<input type="checkbox"/>		
		TORRE, D. ET AL., "Interaction of human plasma fibronectin with viral proteins of human immunodeficiency virus", Fems. Immunol. Med. Microbiol., 1994, Vol./Issue No. 8-2, pp. 127-131	<input type="checkbox"/>		
		TSAL, SCHWICKWANN ET AL., "Differential binding of erythroid and myeloid progenitors to fibroblasts and fibronectin", Blood, 1987, Vol./Issue No. 69-6, pp. 1587-1594	<input type="checkbox"/>		
		VALSESIA-WITTMANN, S. ET AL., "Modifications in the Binding Domain of Avian Retrovirus Envelope Protein to Redirect the Host Range of Retroviral Vectors", J. Virol., 1994, Vol./Issue No. 68:7, pp. 4609-4619	<input type="checkbox"/>		
		VAN BEUSECHEM, V.W., ET AL., "Long-Term Expression of Human Adenosine Deaminase In Rhesus Monkeys Transplanted with Retrovirus-Infected Bone-Marrow Cells", Proc. Natl. Acad. Sci. USA 1992 Vol./Issue No. 89 pp. 7640-7644	<input type="checkbox"/>		
		VAN DER SLUIJS, "Differential Adherence of Murine Hematopoietic Stem Cell Subsets to Fibronectin", Experimental Hematology, 1994, Vol./Issue No. 22, pp. 1236-1243	<input type="checkbox"/>		
		VARMUS, HAROLD, "Retroviruses", SCIENCE, June 10, 1988, pp. 1427-1434	<input type="checkbox"/>		
		VERFAILLIE, C.M., ET AL., "Differentiation of Primitive Human Multipotent Hematopoietic Progenitors Into Single Lineage Clonogenic Progenitors is Accompanied by Alterations in Their Interaction with Fibronectin" J. Exp. Med. 1991 Vol./Issue No. 174 pp. 693-703	<input type="checkbox"/>		
		WAGNER, J.E. ET AL., "Transplantation of Umbilical Cord Blood After Myeloblastic Therapy: Analysis of Engraftment", Blood, 1992, Vol./Issue No. 79:7, pp. 1874-1882	<input type="checkbox"/>		
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		WAGNER, J.E. ET AL., "Allogenic umbilical cord blood transplantation: Report of results in 26 patients", Blood, 1993, Vol./Issue No. Abstract, pp. 82-86a			
		WATT ET AL., "Adhesion Receptors are differentially expressed on Developing Thymocytes and Epithelium in Human Thymus", Experimental Hematology, 1992, Vol./Issue No. 20, pp. 1101-1111			
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		XU, L.C., ET AL., "Long-term in vivo expression of the human glucocerebrosidase gene in nonhuman primates after CD34+ hematopoietic cell transduction with cell-free retroviral vector preparations", Proc. Natl. Acad. Sci. USA, 1995, Vol./Issue No. 92, pp. 4372-4376			
		XU, LINCHENG, ET AL., "Correction of the enzyme deficiency in hematopoietic cells of Gaucher patients using a clinically acceptable retroviral supernatant transduction protocol", Experimental Hematology, 1994, Vol./Issue No. 22, pp. 223-230			
		YAO ET AL., "Primary myoblast-mediated gene transfer: persistent expression of human factor IX in mice", Gene Therapy, 1994, Vol./Issue No. 1:2, pp. 99-107			
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